K022434
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AUG 0 5 2002

BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Endoscopic Technologies C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	(978) 262 - 4866
Fax:	(978) 262 - 4878
Contact Person:	Beth A. Zis, R.A.C.
Date of Preparation:	June 17, 2002

B. Device Name

Trade Name:	Bard® UltraView™ Multiple Band Ligator
Common/Usual Name:	Ligator, Esophageal
Classification Name:	Hemorrhoidal Ligator

C. Predicate Device Name(s)

Trade Name:	Wilson-Cook® Ten Shot Multi-Band Ligator Bard® Steigmann-Goff™ Ligator

D. Device Description:

The Bard® UltraView™ Multiple Band Ligator is comprised of a ligating unit that fits over the distal end of an endoscope with seven premounted natural rubber latex ligating bands. The ligating unit is attached to the handle by the activating cable sheath. The bands are 1.9 mm thick with a 5.1 mm outer diameter and a 2.0 mm inner diameter.

Three endoscope adapters and a centering sleeve are provided to allow the ligating unit to fit securely on endoscopes ranging from 8.5 mm to 10.8 mm. The small adapter fits 8.5 to 9.3 mm scopes. The medium adapter fits 9.3 to 10.2 mm scopes. The large adapter fits 10.2 to 10.8 mm scopes. No adapter is required for 10.8 to 11.5 mm scopes. A scope gauge is included to determine the required adapter for the endoscope.

E. Intended Use:

The Bard® UltraView™ Multiple Band Ligator is used for endoscopic ligation of esophageal varices.

F. Technological Characteristics Summary:

The proposed Bard UltraView ligator is comprised of similar medical grade plastics, stainless steels and uses the same band material as the predicates.

The design differs from the predicate devices in that the actuation mechanism runs along the outside of the endoscope instead of through the working channel to allow maximum suction into the working channel. The cable sheath attaches to the handle assembly, which can be held in the physician or

assistants hand or mounted to the endoscope insertion sheath outside of the patient. The bands are deployed when the thumb paddle, on the handle assembly, is depressed all the way down. This causes the bands to be pushed/deployed off of the band carrier. Both the predicate devices use a trip wire mechanism located on the handle to pull the band off of the band carrier. The proposed device mounts flush with the tip of the endoscope to allow maximum visualization and is retained with friction fit scope adapters that mount inside of the device. The predicate device tips extend beyond the distal tip of the endoscope and cannot be retracted flush with the distal end of the endoscope.

G. Performance Data

Biocompatibility tests were completed that demonstrate the device is safe for its intended use and patient population. Functionality testing, tensile testing and comparative endoscope aspiration and retention testing has demonstrated that the Bard® UltraView™ is substantially equivalent to the Wilson-Cook® Ten Shot Multi-Band Ligator and the Bard® Steigmann-Goff™ Ligator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 5 2002

Bard Endoscopic Technologies
c/o Dr. Peter N. Ruys
N.V. KEMA
Utrechtseweg 310
NL-6812 AR Arnhem
THE NETHERLANDS

Re: K022434
Trade/Device Name: Bard® UltraView™ Multiple Band Ligator, Model #00700U
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: 78 MND
Dated: June 28, 2002
Received: July 25, 2002

Dear Dr. Ruys:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): TBD K022434

Device Name: Bard® UltraView Multiple Band Ligator

Indications For Use: The Bard® UltraView™ Multiple Band ligator is used for endoscopic ligation of esophageal varices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022434